Efficacy of post-operative analgesia after posterior lumbar instrumented fusion for degenerative disc disease: a prospective randomized comparison of epidural catheter and intravenous administration of analgesics

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Abstract

This prospective study aimed to compare the efficacy of epidural (EDA) versus intravenous (PCA) application of analgesics after lumbar fusion. Fifty-two patients scheduled for elective posterior instrumented lumbar fusion were randomized into two groups. EDA patients received an epidural catheter intraoperatively, and administration of ropivacain and sulfentanil was started after a normal post-operative wake-up test in the recovery room area. PCA patients received intravenous opioids in the post-operative period. Differences between EDA and PCA groups in terms of patient satisfaction with respect to pain relief were not significant. Nevertheless, EDA patients reported less pain on the third day after surgery. There were significantly more side effects in the EDA group, including complete reversible loss of sensory function and motor weakness. There were no major side effects, such as infection or persisting neurological deficits, in either group. The routine use of epidural anesthesia for lumbar spine surgery has too many risks and offers very little advantage over PCA.

Introduction

Effective post-operative pain control is not only a matter of patient satisfaction, it affects the perioperative morbidity after major general, gynecological or thoracic surgeries considerably and shortens the length of hospital stay.[1-4]

Intravenous administration of opioids has proved superior to intramuscular injections in the management of post-operative pain. The introduction of patient controlled analgesia (PCA) has further improved patient satisfaction. The epidural administration (EDA) of analgesics is another effective route to give analgesics during post-operative care. Aggressive pulmonary rehabilitation and early mobilization are promoted by epidural analgesia.[5]

Several studies have compared PCA and EDA in the management of pain after abdominal surgery and gynecological procedures. Patients in the EDA group reported better pain relief. The treatment of chronic back pain patients with longstanding use of analgesics is a difficult challenge after lumbar spine surgery for degenerative disc disease.

The results of post-operative pain therapy after lumbar spine surgery have so far been inconsistent. Joshi and Sucato *et al.* compared PCA (morphine) and EDA (fentanyl) and reported advantages in terms of post-operative pain scores for the patients in the EDA group.[6,7] Other groups found no significant differences between PCA and EDA in the post-operative regimens after spinal fusion.[3,8]

The following exploratory study focuses on the difference between two routes of administration of post-operative analgesics, the epidural and intravenous infusion, after instrumented posterior fusion surgery of the lumbar spine. The aims of the study were to quantify the doses of analgesics given according to the route of administration and evaluate differences in pain assessment and patient satisfaction.

Materials and Methods

Patients scheduled for elective spinal surgery of the lumbar spine for degenerative disc disease were assigned randomly by a computer program to one of two groups (1-12/2006). The hypothesis of the study was that EDA is more effective in comparison to intravenous administration of analgesics for post-operative treatment.

EDA patients (n=29) received an epidural catheter intraoperatively whereas PCA patients (n=23) did not. All patients underwent dorsal instrumented fusion at our institution performed by one of the two authors (TK or TN). There was no patient drop out. Characteristics at baseline are summarized in Table 1. There was no difference in gender distribution between the groups (P=0.41, Fisher's exact test).

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The study was approved by the local ethics committee (Nr. 178-2004) University of Tuebingen, Germany.

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The study was approved by the local ethics committee (Nr. 178-2004). The original application for a blinded study with placement of an epidural catheter and a placebo medication in the PCA group was denied by the local ethics committee on the grounds of poor risk/benefit ratio for this group. Written informed consent was obtained from all participating patients.

Inclusion criteria were defined as: age over 18 years, concurrence of radiological lumbar disc disease and localization of persistent pain under conservative treatment for over three months, elective posterior lumbar instrumented spinal fusion procedure with or without decompression. A standard midline approach was used. All patients received the same protocol for pre-operative preparation. Single dose prophylactic antibiotics were given. The Expedium screw-rod system (Fa. Depuy®) was implanted. Exclusion criteria were defined as: infection, tumor or fracture as indication for surgery, missing informed patient consent, language barrier, mental retardation, pre-operative neurological deficit and known adverse reactions to analgesics. Pre-operative use of opioids and revision procedures were not defined as exclusion criteria.

EDA patients more frequently received a transforaminal lumbar intervertebral fusion (TLIF); however, posterior fusion with anterior lumbar interbody fusion (ALIF) was more common in the PCA group. The differences did not reach statistical significance (Table 1). The decision for one or the other procedure was made according to underlying pathology and the need for decompression of the stenotic segment.

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Surgical technique

After completion of the spinal procedure, a Tuohy needle (20 G, B. Braun, Melsungen, Germany) was placed from the lateral aspect of the incision through a separate skin puncture (Figure 1). The epidural catheter was threaded through the needle and placed in the epidural space under direct vision by the surgeon. The catheter tip was advanced 3 cm cephalad to the level of the instrumentation. The catheters were fixed to the skin with 30 cm adhesive bandage across the back (Fixomull®, Fa. Beiersdorf, Germany). The catheter marking at skin level was documented and checked during dressing changes to watch for catheter dislocation.

After surgery all patients underwent an unremarkable wake-up test in the operating theatre. Afterwards a mixture of ropivacain and sulfentanil was administered via catheter in the recovery room (EDA) starting with a flow rate of 8 mL/h. An infusion pump was used to deliver a continuous flow using a 50 ml syringe (sufentanil 20 μg/4mL + 21 mL NaCl 0.9%+25 mL ropivacain 0.2%). All patients were nursed overnight in an intermediate care unit. Acute pain service checked on the patients, and infusion rate was adjusted to the pain and sensomotory status. All patients were offered additional pain medication on request.

PCA patients received intravenous piritramid using an infusion pump. The treatment was also started in the recovery room. A fixed concentration of 30 mg piritramid (2 ampoules of 2 mL) with 46 mL of NaCl in perfusion syringe was prepared. The starting infusion rate was 5 mL/h (3mg/h). The patients were offered additional bolus doses using PCA pump (2.5 mg) with a blocking time of 10 min. Non-opioids were administered for both groups (metamizol 3*1 g) and non-steroidal anti-inflammatory drugs (diclofenac 2*75 mg). These drugs were given by a structured regimen in the intermediate care facility during the first 24 h after surgery.

If the initial adjustment did not achieve adequate pain control (VAS>5), IV sufentanil was given.

One person not involved in the clincal care of the patients (FH) recorded the following data: dosage of intravenous and epidural medication used, supplementary analgesics (NSAIDs, metamizol, paracetamol) and side effects of medication, pain (visual analog scale), adverse reactions, sleep, appetite and patient satisfaction with the post-operative pain treatment (VAS). Mobility was evaluated by questions concerning walking, climbing stairs and bathroom activities. The same list of items was checked at the day before the procedure, at the day of the operation, and on the 1st, 3rd and 8th day after surgery (primary endpoint). Results on the VAS were transferred into a Numeric Rating Scale (NRS, 0-10). Interval scales were used for the scoring questions (0 = best, 10 = worst). Patients were not aware of the kind of treatment given for post-operative pain therapy before they were anesthetized. All patients received a urinary catheter after they had been anesthetized which was removed 24-48 h after surgery.

Statistical analyses were performed using JMP, version 5.1 (SAS Institute, Cary, NC, USA). The level of statistical significance was set at $P<0.05$. The characteristics of the two regimens were compared using the two-tailed Fisher's exact test, Fisher-Freeman-Halton test, the two-sample t-test or Mann-Whitney U test as appropriate. VAS pain levels were analyzed by ANOVA. The data of this exploratory study were collected with an objective but not with a pre-specified key hypothesis and multiple test adjustment was, therefore, not performed. The 8th day after surgery was specified as single primary endpoint of the study. All other endpoints were considered subsidiary and the interpretation of the results must be considered exploratory.

Table 1. Baseline characteristics of the patients (min.-max. in parentheses).

Variable	Epidural Group 1 (n=29)	Intravenous Group 2 (n=23)	P
Mean age (years)	57 (22-80)	62 (28-86)	0.24
Gender (female/male)	15/14	9/14	0.36
Median duration of surgery (min)	168 (68-279)	163 (69-556)	0.72
Median number of fused levels	1 (1-8)	2 (1-11)	0.083
Iliac crest bone harvesting	15/29	7/23	0.16
Type of surgery			
Posterior fusion	4	2	
Posterior fusion + ALIF	7	13	0.07
TLIF	18	8	

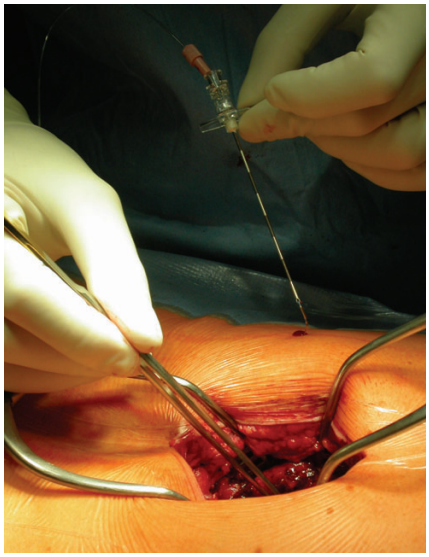

Figure 1. Placement of the epidural catheter through a separate skin puncture with the Tuohy needle.

Results

The levels of pain (VAS) decreased significantly during the course of the hospital stay for both groups (ANOVA; time effect, P=0.027, F test). The mean pre-operative score was higher for EDA patients 5.0±2.9, and 3.5±3.0 for PCA patients, respectively. There was an advantage for the pain management in the EDA group which showed a tendency to statistical significance at day 3 (P=0.064) (Table 2).

Mean duration of EDA administration was 45.0±16.7 h. The average infusion rate of the ropivacain/sulfentanil combination was 9.8±2.0 mL/h.

The cumulative doses for the different analgesics used are summarized in Table 3. PCA patients received significantly higher doses of sufentanil intravenously. The doses of adjuvant analgesics given did not differ between both groups. PCA patients used fentanyl transdermal patches significantly more often during the observation period.

The following minor side effects were recorded for EDA patients: loss of sensory function (n=6), motor weakness (n=3), failure or displacement of EDA catheter (n=3).

In the PCA group, three out of 23 patients complained of nausea and vomiting. Cardiopulmonary reactions were not reported in either group. Side effects occurred significantly more often in the EDA group but all resolved completely within hours. The EDA-administration was stopped until the documented normalization of the sensory motor function and continued thereafter. There was no difference in the length of hospital stay. Mean discharge time was 13.9±6.3 days after surgery for the EDA group and 13.4±2.4 for the PCA patients (P=0.91, t-test, logarithmic transformation), respectively. The inpatient period for the procedure advised by the hospital administration was 14 days.

Patient satisfaction with post-operative pain therapy was rated higher in the EDA group but failed to meet statistical significance (Table 4). Selected answers to items of the questionnaire are listed in order of the time of evaluation.

Pre-operative situation

One patient in each group was not able to rise from a chair without assistance. One further patient in the epidural group was in need of help for personal hygiene preparations. Climbing stairs was not possible for one EDA and 3 PCA patients. EDA patients reported being well over all significantly more often (P=0.019)

Day of surgery

All patients were helped to carry out hygiene tasks. EDA patients reported "being well over all" significantly more often about "being well over all" (P=0.019). Most patients in both groups suffered from loss of appetite (53% vs. 60%, P>0.05). There was no difference in results of VAS and mobilization between groups.

First day after surgery

Analysis did not show evidence of differences between the groups in terms of pain, mobilization, need of assistance for activities of daily living, appetite, problems during physical therapy or general well being. There were significantly fewer reports of disturbances of night sleep due to pain in EDA patients (26% vs. 80%, P=0.005). Satisfaction with the pain management was rated higher in the PCA group (2.8±2.7 vs. 1.8±1.8, P=0.18).

Third day after surgery

Scores were assessed after removal of the epidural catheter. Suffering from pain was rated lower for the EDA group, but did not gain statistical significance (P=0.064). Mobilization also improved faster for EDA patients. Eighty-five percent of the EDA patients were able to transfer and walk short distances without help in comparison to 61% in Group 2 (P=0.058). Most of the Group 1 patients were independent in the bathroom (85% vs. 52%, P=0.014).

Eighth day after surgery

EDA patients showed an advantage when climbing stairs independently (74% vs. 40%, P=0.034). These patients reported loss of appetite less frequently (P=0.044).

There was no difference in answers to general well being, the course of the hospital stay, the level of pain at that moment and the overall satisfaction with pain management.

Mean costs for all analgesics used during the hospital stay were significantly higher for EDA patients (31.07±21.72 euros vs. 5.10±4.14 euros, P<0.0001). These numbers are based on the prices of our hospital pharmacy in euros and do not include auxiliary costs.

Table 2. Results of pain assessment after transforming the VAS-markings of the patients into the numeric rating scale (mean ± SD, numeric rating scale 0-10).

	Epidural Group 1 (n=29)	Intravenous Group 2 (n=23)	P
Day before surgery	5.0±2.9	3.6±3.0	0.093
Day of surgery	4.0±3.7	5.9±4.2	0.292
1st post-op. day	3.8±2.9	3.5±2.9	0.733
3rd post-op. day	3.0±2.6	4.5±3.0	0.064
8th post-op. day	2.2±2.3	3.3±3.0	0.213

Table 3. Cumulative doses of all analgesics administered during the observation period (mean ± SD).

Medication	Morphine equivalents	Epidural Group 1 (n=29)	Intravenous Group 2 (n=23)	P
Epidural				
Ropivacain (g)		1.19±1.47	-	-
Sufentanil (μg)	1000	2.24±0.98		
Intravenous				
Sufentanil (μg)	1000	7.59±23.21	14.24±20.25	0.053
Piritramid (mg)	0.7	24.09±92.36	53.55±120.10	0.14
Paracetamol (g)		0.91±1.10	1.28±1.53	0.32
Metamizol (g)		8.38±7.42	7.64±6.67	0.71
Enteral/rectal				
NSAID (g)		1.44±0.62	1.42±0.85	0.93
Morphine (mg)	1	61.83±188.68	130.44±343.58	0.30
Tramadol (g)	0.1	0.50±0.64	0.40±0.51	0.50
Transdermal				
Fentanyl (μg)	100	1.72±9.28	20.09±57.65	0.045

Table 4. Patient satisfaction with pain therapy for both groups (mean ± SD 0=excellent, 10=very poor).

	Epidural Group 1 (n=29)	Intravenous Group 2 (n=23)	P
Day of surgery	1.88±0.54	2.04±0.88	0.874
1th post-op. day	2.28±0.45	2.63±0.51	0.602
3rd post-op. day	2.66±2.52	3.30±2.95	0.416
8th post-op. day	1.98±2.40	3.39±3.44	0.153

Discussion

Potential undertreatment of pain in the post-operative period because of concerns of safety and complications, such as opioid related respiratory depression, has been reported.[5] The proportion of patients with inadequate pain therapy is reported to be up to one half.[5] This risk is especially high in patients who have undergone surgery for chronic low back pain. These patients are often accustomed to treatment with potent analgesics including opioids. The introduction of the epidural application route for analgesics was very successful for the treatment of post-operative pain after general surgery or gynecological procedures.[9] Following spinal surgery, this administration route can interfere with the post-operative neurological observation of the patient, and increase the risk of delay in diagnosis and treatment of post-operative complications because of masking the symptoms.[4] Some authors recommend delaying the initiation of the epidural analgesia until the next day and to, therefore, minimize interference with post-operative neurological observation.[1]

In many centers, PCA is the standard technique of choice for pain therapy after spinal procedures. Since this method complements the individual variation of pain perception, it is superior to continuous intravenous administration. However, a PCA bolus-on-demand regimen does not address the issue of pre-emptive pain treatment, especially the first night after surgery. This issue is reflected in our results of less night sleep disturbance in the EDA group with continuous opioid administration.

Joshi *et al.* found significant lower pain scores after laminectomy for patients with continuous epidural administration of fentanyl compared to intravenous morphine infusion.[6] After anterior scoliosis correction, patients

benefit from epidural ropivacain infusion through improved analgesia, less vomiting/nausea and earlier return of bowel function.[1,7] The main advantage of epidural application is the lower opioid dosage necessary to achieve pain relief and, therefore, less general opioid side effects.[9] The biggest drawback is the presence of an additional foreign body in the surgical area. There is the potential risk of iatrogenic infection and delay in the treatment of post-operative complications, such as epidural hematoma, as the cause of the development of sensory or motor impairment.

This study has limitations in that, despite the randomization, the groups differ in fusion length. However, there was no significant difference in median pre-operative pain score (VAS) between the two groups. Since there was also no statistical difference in reported pain levels reported at day 8 after surgery, we assume that the comparison of both groups is correct and results were not altered by confounding variables. It was surprising that the only statistical tendency on the NRS numbers was found at day 3, since the EDA was removed after an average 45 h.

The incidence of minor side effects in this study was minimal. Despite the small numbers, every report of a neurological deficit in a patient soon after spinal surgery is alarming (especially to the responsible surgeon) and may cause additional diagnostic efforts and costs, for example, for a control CT scan to rule out complications such as epidural hematoma. Fortunately, we did not observe major complications like infection or neurological deficits, as reported previously.[10] Minor advantages for the EDA patients in the mobilization areas might be caused by less sedation through the systemic opioid effects. These results are in contrast to the numbers of Fisher *et al.* They could not achieve earlier mobilization in the EDA group.[3] The use of two epidural catheters provided a better post-operative analgesia with fewer side effects and higher patient satisfaction after anterior scoliosis correction in another study.[1]

We did not confirm the catheter position radiographically, as suggested in the literature.[1,3] We felt there was no need for this as we positioned the catheter under direct vision.

The use of patient controlled epidural infusion did not show significantly better results than another earlier report. Eleven out of 39 patients were reported to cross over to a PCA regimen and there was also no difference in patient satisfaction.[3]

Different medication dose regimens have been reported for PCA and EDA in the literature.[1,3,8,11,12] Since we had already observed sensory and motor impairment, we are sure we did not underdose EDA in our patients. However, there may be another more effective regimen. The combination of a local anesthetic plus opioid seems to be more effective than opioids alone.[1,8] Urinary retention is a frequent problem of EDA use. Since all our patients received Foley catheterization during the pre-operative preparation we did not have any such problems.

The length of the hospital stay is not a valid measure of treatment outcome because of the economic confounders, and the discharge of our patients was more influenced by the grouping of the patient (DRG-diagnosis related groups) than by pain and mobilization of the patients. Since there were no striking statistical differences between either regimen in this exploratory study, they may both be selected for post-operative pain management after lumbar instrumented spinal fusion according to the preferences of the staff and the patient.

The use of epidural anesthesia routinely for spine surgery provides too many risks and very little additional benefit from PCA. Neurological deficit confusing the neurological exam, and increased costs are the major reasons why we do not use epidural anesthesia after lumbar spine fusion.

The pre-operative placement of the EDA catheter and the administration of opioids during surgery contribute to more stable hypotension and less bleeding during the procedure and these may be advantages in EDA treatment.[12] Since we placed the catheter after completing the spinal procedure we have not proved this possible positive effect of EDA.

Conclusions

Epidural administration of analgesia is an effective route for post-operative pain management after lumbar spinal instrumented fusion. But patients in the EDA group experienced significantly more minor side effects which demanded more attention by the surgeon in charge and the nursing staff to avoid delay in case of possible surgical complications. Patient satisfaction with post-operative pain treatment was equally positive with the intravenous regimen. At present we only use PCA in the post-operative period after lumbar spine fusion.

References

1. Blumenthal S, Borgeat A, Nadig M, et al. Postoperative analgesia after anterior correction of thoracic scoliosis: a prospective randomized study comparing continuous double epidural catheter technique with intravenous morphine. Spine 2006;31:1646-51.
2. Feldstein G, Ramanathan S. Obstetrical lumbar epidural anesthesia in patients with previous posterior spinal fusion for kyphoscoliosis. Anesth Analg 1985;64:83-5
3. Fisher CG, Belanger L, Gofton EG, et al. Prospective randomized clinical trial comparing patient-controlled intravenous analgesia with patient-controlled epidural analgesia after lumbar spinal fusion. Spine 2003;28:739-43.
4. Yukawa Y, Kato F, Ito K, et al. A prospective randomized study of preemptive analgesia for postoperative pain in the patients undergoing posterior lumbar interbody fusion: Continuous subcutaneous morphine, continuous epidural morphine, and diclofenac sodium. Spine 2005;30:2357-61.
5. Kumar RJ, Menon KV, Ranjith TC. Use of epidural analgesia for pain management after major spinal surgery. J Orthop Surg 2003;11:67-72.
6. Joshi GP, McCarrol SM, O´Rourke K. Postoperative analgesia after lumbar laminectomy: Epidural fentanyl infusion versus patient controlled intravenous morphine. Anesth Anal 1995;80:511-4.
7. Sucato DJ, Duey-Holtz A, Elerson E, Safavi F. Postoperative analgesia following surgical correction for adolescent idiopathic scoliosis: a comparison of continuous epidural analgesia and patient-controlled analgesia. Spine 2005;30:211-7.
8. Cohen BE, Hartman MB, Wade JT, et al. Postoperative pain control after lumbar spine fusion. Patient-controlled analgesia versus continuous epidural analgesia. Spine 1997;22:1892-6.
9. Grass JA. Fentanyl: Clinical use as postoperative analgesic – epidural/intrathecal route. J Pain Symptom Manage 1992;7:419-30
10. Müller M, Burger C, Andermahr J, et al. Spondylodiscitis after perioperative peridural catheter. Anaesthesist 2004;53:1189-94.
11. Eilers K, Schenk M, Putzier M, et al. Use of peridural catheters in the treatment of postoperative pain after spinal instrumented fusion: an experience report. Z Orthop 2002;140:621-5.
12. Yoshimoto H, Nagashima K, Sato S, et al. A prospective evaluation of anaesthesia for posterior lumbar fusion: the effectiveness of preoperative epidural anesthesia with morphine. Spine 2005;30:863-9.